K101812

510(k) SUMMARY

BLACKSTONE CONSTRUX MINI™ PEEK SPACER SYSTEM

Sponsor:	Orthofix, Inc. 1720 Bray Central Dr. McKinney, TX 75069
	SEP 27 2010
Registration Number:	2183449
Contact Person:	Russell Johnson, Regulatory Affairs Specialist
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Date Prepared:	9-20-2010
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Manufacturer:	Orthofix, Inc. 1720 Bray Central Dr. McKinney, TX 75069
Registration Number:	2183449
Contract Manufacturer:	Marox Corporation 373 Whitney Avenue Holyoke, MA 01040-2766
Trade Name:	Construx Mini Spacers
System Name:	Construx Mini PEEK Spacer System
Product Codes:	ODP – Intervertebral Fusion Device with Bone Graft, Cervical MQP – Spinal Intervertebral Body Fixation Orthosis
Common Name:	Intervertebral body fusion device

K101812

Regulatory Classification:	Class II - 888.3080 - Intervertebral Body Fusion Device 888.3060 - Spinal Intervertebral Body Fixation Orthosis
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Blackstone Medical, Inc. Construx Mini (K051246 SE 6-14-05) Spinal Elements, Inc., Crystal Device, K073351 SE 1-4-2008 Custom Spine, Inc., Pathway ACIF, K092904 SE 12-22-2009 DePuy Spine, Inc. Bengal™ System, K081917 SE 5-22-2009

Intended Use / Indications for Use

When used as a cervical intervertebral body fusion device, the Construx Mini PEEK System is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Construx Mini PEEK System is intended for use with autograft and supplemental internal fixation, e.g.: the Blackstone Medical Ascent™ or Ascent LE™ POCT System.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Construx Mini PEEK System in the cervical spine.

The Construx Mini PEEK device is used singly and is implanted using an anterior approach.

When used as a Partial Vertebral Body Replacement (VBR) System, the Construx Mini PEEK System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Construx Mini PEEK System is also indicated for treating fractures of the thoracic and lumbar spine.

The Construx Mini PEEK System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The Partial VBR device is intended to be used with autograft or allograft.

The Construx Mini PEEK System is intended for use with internal fixation. The supplemental internal fixation system that may be used with the Construx Mini PEEK

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System is the Blackstone Medical Spinal Fixation System (SFS) or the Firebird Spinal Fixation System.

Technological Characteristics

The Construx Mini PEEK Spacer System components consist of:

1) A PEEK Spacer
2) cp Titanium Markers

The Construx Mini Spacer System is a Cervical IBFD device that is implanted using anterior surgical approach with the intention is to achieve intervertebral spinal fusion. In addition, the Construx Mini is intended to contain autologous bone graft to facilitate intervertebral fusion. The Construx Mini performance data, in combination with a dimensional comparison to predicate devices and testing, has been used to demonstrate substantial equivalence with devices that are cleared for both Cervical IBFD and Partial VBR indications.

The testing conducted for the Construx Mini included Static Compression, Dynamic Compression, Static Torsion, Dynamic Torsion, and Subsidence. The testing was conducted under ASTM F2077-03 and ASTM F2267-04 guidance.

Substantial Equivalence

The Construx Mini Spacer System has been demonstrated to be substantially equivalent to predicate devices in their intended use, indications for use, technological characteristics and principles of operation. Any differences between the Construx Mini Spacer System and its predicates do not present new issues of safety or effectiveness, therefore, the Construx Mini Spacer System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthofix, Inc.
% Mr. Russell Johnson
Regulatory Affairs Specialist
1720 Bray Central Drive
McKinney, Texas 75069

SEP 27 2010

Re: K101812
Trade/Device Name: Construx Mini™ PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: June 25, 2010
Received: June 29, 2010

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101812

Device Name: Construx Mini™ PEEK Spacer System

SEP 27 2010

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101812